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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,903	05/06/1999	PETER JAMES WATTS	WC131	1775

7590 07/16/2002

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/16/2002 25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/269,903

Applicant(s)

WATTS, PETER JAMES

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-45 and 48-57 is/are rejected.
- 7) ☒ Claim(s) 46 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 5/16/2002 has been entered.

Specification

The amendment filed 5/16/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "poly (ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.2)", "poly (ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1:2:0.1" and "poly ethyl acrylate, methyl methacrylate) 2:1". Examiner has considered Applicant's evidence, however, in order for evidence to be relevant, the evidence must have a date which is before the filing date of the Application and is as close to the filing date as possible. Applicant is required to cancel the new matter in the reply to this Office Action or provide relevant evidence supporting the addition of said material to the Specification.

Claims 46,47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims subject to update of the prior art search herein.

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Claim 55, line 9, "than" should be "than".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-45, 48-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising pellets and drugs having a free acid group, a pKa in the range of 2.0-9.0, and is an alkali metal salt that has a higher solubility at pH 4.5-8 than a free acid form of the drug, where the means of releasing the drug in the terminal ileum or colon is by the use of the disclosed coating compounds and a inner core does not reasonably provide enablement for means not specifically disclosed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. As indicated above, the Specification appears to give limited direction as to the suitable components of the claimed invention. As such, it appears that a skilled artisan would be required to do undue experimentation in order to determine what other compounds have the desired characteristics of the invention, i.e. whether the coating compound will prevent release of the drug until it reaches the colon.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

A specification which describes the invention does not necessarily also enable one of ordinary skill in the art to make or use the claimed invention. See *In re Armbruster*, 185 USPQ 152 (CCPA 1975). As shown by Applicant's Declaration and comparison with a prior art composition, even though, similar coating compound are recited in the Specification and the prior art compositions, the results are not the same. Given that a given membrane must be of sufficient thickness, pH solubility and non-degradeability to pass through the stomach and small intestines but be able to be dissolved/disintegrated in the colon, other than the examples provided, one of ordinary skill in the art would have to do undue experimentation in order to determine what other membranes would be suitable to make and/or use the claimed invention and the appropriate thickness, pH solubility and degradability.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the Specification to insert generic definitions, however, the evidence submitted does not appear to be sufficient relevant to show that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 29-45, 48-57 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting one or more of the following essential elements or steps, such omission amounting to a gap between the elements or steps. See MPEP § 2172.01. The omitted elements or steps are: a rate controlling membrane which prevents release of the drug until the composition reaches the colon which is determined by the type of coating compound, its pH

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solubility and thickness (See Claims 1-17, 19, 21-26), an effective amount of a drug which is effective in treating the claimed intestinal diseases (See Claim 19).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Although pH solubility and degradability may be inherent properties, thickness of the membrane is not inherent and, in fact, can have an effect on pH solubility and degradability as the thicker the membrane the longer it takes for the enzymes and acid to leach into the membrane and dissolve/disintegrate the membrane. Further, the type of the membrane, its pH solubility and thickness appear to be critical as the composition must be able to pass through the stomach, small intestines to reach the colon. As indicated above, it appears from the Declaration submitted by Applicant, that the above are critical to obtain a result which is different from the prior art compositions.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

July 15, 2002


ALLEN J. ROBINSON
PRIMARY EXAMINER

